

Message Text

PAGE 01 STATE 205330

11
ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-05

EB-07 COME-00 /066 R

66616
DRAFTED BY DHEW/FDA/JRWEINROTH
APPROVED BY OES/APT/BMP:MBEAUBIEN
DHEW/OIH/MACODDING
EA/ANP:MMICHAUD (INFO)
EA/J:DBROWN (INFO)
EUR/NSC-IG:JROUSE (INFO)
AF/S:RDOLS (INFO)
NEA/IRN:BMORTON (INFO)
NEA/IAI:WSMITH (INFO)
ARA/MEX:GFALK (INFO)

----- 003040

R 282132Z AUG 75
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA
AMEMBASSY HELSINKI
AMEMBASSY PARIS
AMEMBASSY TEHRAN
AMEMBASSY TEL AVIV
AMEMBASSY ROME
AMEMBASSY TOKYO
AMEMBASSY MEXICO
AMEMBASSY THE HAGUE
AMEMBASSY PRETORIA
AMEMBASSY MADRID
AMEMBASSY STOCKHOLM
AMEMBASSY BERN
AMEMBASSY LONDON

UNCLAS STATE 205330

E.O. 11652: N/A
TAGS: ETRD, OGEN, TBIO, AS, FI, FR, IR, IS, IT, JA, MX,
NL, SF, SP, SW, SZ, UK.
UNCLASSIFIED

PAGE 02 STATE 205330

SUBJECT: FDA ADVISORY - DEFECTIVE HEART VALVES

1. FDA ADVISES THAT HEART VALVES (AORTIC AND MITRAL) MANUFACTURED
BY SHILEY LABORATORIES, INC. 17600 GILLETTE AVENUE SANTA ANA,

CALIF. 92705, "FABRICATION ORDER NUMBERS" 07612, 09211,
01-791 ARE DEFECTIVE IN THAT THE DEVICES HAVE FAILED DUE TO
SEPARATION OF THE LOWER STRUT FROM THE MAIN VALVE BODY OF
OF IMPLANTED VALVES. THREE SUCH FAILURES HAVE OCCURRED RESULTING
IN TWO KNOWN DEATHS.

2. EACH VALVE IS INDIVIDUALLY SEALED IN A SMALL PLASTIC BAG
WHICH IN TURN IS CONTAINED IN A PLASTIC BOX. ALSO CONTAINED IN
THE PLASTIC BOX IS AN INSTRUCTIONAL BROCHURE ENTITLED: "SHILEY-
?94-SHILEY CARDIAC VALVE PROSTHESIS CARE AND HANDLING
INSTRUCTIONS" AND AN IMPLANTATION DATA CARD. THE OUTER LABELING
ON THE PLASTIC BOX DESCRIBES THE DEVICE, ITS SIZE, TYPE OF VALVE
DISC, AND ITS SERIAL NUMBER. IN ADDITION, THE LABEL STATES
THAT THE VALVE IS NON-STERILE AND WAS MANUFACTURED BY SHILEY
LABORATORIES, INC. THE FIRM USES FABRICATION ORDER NUMBERS
TO INTERNALLY IDENTIFY "BATCHES" OF VALVES. EACH VALVE ITSELF
IS IDENTIFIED WITH A 3 OR 4 DIGIT SERIAL NUMBER WHICH FOLLOWS
A SEQUENCE OF NUMBERS AND LETTERS FOR IDENTIFYING THE VALVE
SIZE AND TYPE (E.G. 29MBRP5071 - THE 29 REPRESENTS THE SIZE OF
THE VALVE OPENING IN MILLIMETERS, MBRP REPRESENTS MITRAL SUPRA
ANNULAR SEWING RING, PYROLITIC CARBON DISC, AND 5071 REPRESENTS
THE 4 DIGIT SERIAL NO.). NOTE - THE FIRM IS RECALLING BY
INDIVIDUAL SERIAL NUMBERS OF NON-IMPLANTED VALVES.

3. FOREIGN CONSIGNEES AS FOLLOWS:

A. E. STANSEN AND CO. PTY. LTD. 31MBP956
P.O. BOX 118 MOUNT WAVERLEY
VICTORIA 3149 AUSTRALIA

INSTRUMENTARIOU 29MBRP4740
HOSPITAL & LABORATORY DIVISION 29MBP1707
ELIMAENKATU 22 31MBRP4026 29MBP112
0
HELSINKI, 51, FINLAND

TRANSPORTS CLASQUIN 29MBRP5090 31ABP794
UNCLASSIFIED

PAGE 03 STATE 20530

AIRPORT AT LYON/BRON 29MBRP5095
FOR ACCOUNT OF CLIMO S.A. 29MBRP5097
39, BD AMBROISE PARA 29MBRP5107
69008 LYON, FRANCE 29MBRP5112
29MBRP5113
29MBRP5114
29ABP2258
29ABP2259
31MBRP4098

PAHLAVI UNIVERSITY (IRAN BEHDASHT TEHERAN,
IRAN) 29ABP1091
DEPARTMENT OF SURGERY 29MBRP1469

(OPEN HEART SURGERY)
SHIRAZ, IRAN

QUEEN PAHLAVI FOUNDATION 29MBRP4755
TEHERAN 29MBRP4765
31MBRP4078

ORDER OF: BANK OMRAN
ISTANBUL AVE.
TEHERAN, IRAN

IRAN BEHDASHT CO. LTD. 29MBP1876
118-122 TAKHTE JEMSHID AVE. WEST
TEHRAN, IRAN

UNIVERSITY OF TEHERAN 31MBRP1494
FACULTY OF MEDICINE
TEHERAN UNIVERSITY
TEHERAN, IRAN

MEDTECHNICA LTD. 29MBP1718
P.O.B. 2695
18A KING GEORGE ST. (ALMONIT LN)
TEL-AVIV ISRAEL

GOVERNMENT OF ISRAEL SUPPLY MISSION 31MBRP4667
C/O RANDY INTERNATIONAL LTD.
147-95 FARMERS BLVD.
UNCLASSIFIED

PAGE 04 STATE 205330

JAMAICA NEW YORK 11343
#SINCE THIS UNIT WAS SHIPPED TO A
DOMESTIC ADDRESS, IT IS ALSO
LISTED ON THE DOMESTIC LIST.

P. BARENZO 29MBRP4367 31AB236
FORLANINI AIRPORT 29MBRP4369 29MBR103
9
MILANO, ITALY 29MBRP4712
29MBRP4713
29MBUP510
31MBRP4040
31MBRP4041
31MBRP4046

BOSA 31MBR628
VIA REVERE 16 31MBR631
MILANO, ITALY

SENKO MEDICAL TRADING CO. 29MBRP5166
23-13 3-CHOME HONGO
BUNKYO-KU 29ABP2428

TOKYO, JAPAN 29MBP1703
29MBP1863
31MBP1634
31MBP1652
31MBP1718 29MBP1286

SOLD TO SENKO MEDICAL 29MBP1999
TRADING CO.

23-13 3-CHOME HONGO 29MBP2000
BUNKYO-KU 29MBP2005

TOKYO JAPAN

SHIPPED TO:

MR. HIDEO UNO

11270 #-6534 -;3.

CULVER CITY, CALIFORNIA 90230

##SINCE THESE UNITS WERE SHIPPED TO A

DOMESTIC CONSIGNEE, IT IS ALSO

LISTED ON THE DOMESTIC LIST.

PROVEEDORA CLINICA 29MB1727
UNCLASSIFIED

PAGE 05 STATE 205330

PUEBLA NO. 109 29MB1728
3 178,- :94\$9?- 31MB1280
MEXICO 7 D.F. 31MB1281
31MB1287
N. V. HANDELSMAATSCHAPPIJ HILEKES 29MBRP4673
STARGARDLAAN 13 29MBRP4675
POSTBUS 202 P.O. BOX 202 29MBRP4676
BUSSUM HOLLAND 29MBRP4679
29MBRP4680
29MBRP4778
29MBRP4839

N.V. HANDELSMAATSCHAPPIJ HILEKES 29ABP2294
31MBP979 29ABP2309 31MBP1693
31MBRP1482 29ABP2310 31MBP1738
31MBRP1905 29ABP2356 31MBRP402

2

29MBP1251 (IMPLANTED)

FREDRICK C. MARCUS & CO. LTD. 29MBRP4684
7TH FLOOR MONTE CARLO 29MBRP4685 (IMPLANTE
D)
HEERENGRACHT FORESHORE 29MBRP4686
CAPE TOWN, SOUTH AFRICA 31MBRP4031
31MBRP4032
31MBRP4062

PRODUCTOS MEDICO-QUIRURGICOS S.A. 29MBRP4348 (IMPLANTE
D)
C/O BAKUMAR S.A. 29MBRP4693
RAMBLAS 30 29MBRP4698

BARCELONA 6 SPAIN 29MBRP4723

29MBRP5075
29MBRP5194
29MBP1869
29MBP1871
29MBP1872
29MBP1659

WILSON COMPANY A.B. 31MBUP514

FACK 10250

UNCLASSIFIED

PAGE 06 STATE 205330

STOCKHOLM 27 SWEDEN

HILKES MEDICAL A.G. 29MBRP4355 (IMPLANTE

D)
STEINHAUSERSTRASSE 23 31MBRP4057
6301 ZUG 31MBRP4348
SWITZERLAND

HAUSMANN INC. 29MBP2105

MARKTGASSE 11
CH9001 ST. GALL
SWITZERLAND

CHAS. F. THACKRAY LTD. 29MBRP4644

C/O MORRISON AIR GROUP 29MBRP4818
LEEDS/BRADFORD AIRPORT 29MBRP4821
YEADON NR. LEEDS ENGLAND 29MBRP5133

29MBRP5151
33XMBRP105
31MBRP1315 31MBRP3396 (IMPLANTE
D)
31MBRP2034 31MBRP4001
31MBR636 31MBRP4002
31MBR639 31MBRP4011
31MBR634 31MBRP4014
31MBR647 31MBRP4018
31MBR646 (IMPLANTED) 31MBRP4020 (IMPLANTE

D)
29AB669 31MBRP4367
29MBR927 31MBRP4369
31MBRP4355

4. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY ARE FAMILIAR WITH DETAILS OF ADVISORY
AND MAY ALSO WISH TO NOTIFY HOST GOVERNMENT CONTROL AUTHORITIES
EXERCISING JURISDICTION OVER SUCH DEVICES. ANY QUESTIONS
REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE FIRM.
INGESOLL

UNCLASSIFIED

<< END OF DOCUMENT >>

Message Attributes

Automatic Decaptioning: X
Capture Date: 26 AUG 1999
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD & DRUG REGULATIONS, MEDICAL EQUIPMENT, RECALL
Control Number: n/a
Copy: SINGLE
Draft Date: 28 AUG 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE205330
Document Source: ADS
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH
Enclosure: n/a
Executive Order: N/A
Errors: n/a
Film Number: D750299-0864
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750898/baaaaaaaaai.tel
Line Count: 271
Locator: TEXT ON-LINE, TEXT ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 5
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: hartledg
Review Comment: n/a
Review Content Flags:
Review Date: 02 JAN 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <02 JAN 2003 by ReddocGW>; APPROVED <23 JAN 2004 by hartledg>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
06 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: <DBA CORRECTED> gwr 971008
Subject: n/a
TAGS: ETRD, OGEN, TBIO, AS, FI, FR, IR, IS, IT, JA, MX, OGEN
To: CANBERRA
HELSINKI
PARIS
TEHRAN
TEL AVIV
ROME

TOKYO
MEXICO
THE HAGUE
PRETORIA
MADRID
STOCKHOLM
BERN
LONDON

Type: TE

Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006